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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

Appl. No.:	09/638,102
Filed:	August 11, 2000
Applicant:	David C. Schwartz
Title:	Chemical Screening System Using Strip Arrays
Art Unit:	1641
Examiner:	Davis, Deborah A.
Docket No.:	960296.97133

APPELLANT'S BRIEF ON APPEAL

MS Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant, David C. Schwartz, having filed a timely Notice of Appeal in the above-identified patent application, hereby submit this brief.

I. REAL PARTY IN INTEREST

The real party in interest is the Wisconsin Alumni Research Foundation.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 2, 5 - 7 9 - 13, and 35 are allowed. Claims 14 - 33 are withdrawn from consideration. Claims 41 and 43 - 52 have been rejected. Appeal is taken with respect to claims 41 and 43 - 52.

IV. STATUS OF AMENDMENTS

No amendments were made in response to the final office action. All amendments have therefore been previously entered.

V. SUMMARY OF THE INVENTION

The invention recited in the claims under appeal is a kit for producing customized chemical sampling arrays. Chemical sampling arrays are arrays of different chemical sampling compounds arranged in a regular pattern. Each sampling compound in the array is selected to bond with a different substance that may be part of a material to be analyzed. These devices are used, for example, in genetic research, where the sampling compounds may be different oligonucleotides at least one of which is expected to hybridize with portions of a genetic material to be tested. Information about the make-up or other attributes of the genetic material may be determined by analyzing the locations of hybridization in the array.

In the prior art, chemical sampling arrays were developed either directly by producing planar arrays of different sampling compounds using masking techniques, or by placing sampling compounds on beads and then arranging the beads into arrays. Masking techniques for forming arrays, although effective, do not allow a user to vary the chemical sample compounds in the array, and therefore do not provide sufficient flexibility for researchers to design experiments. Bead systems rectify the problem of flexibility. However, because the beads are extremely small, assembling the beads into arrays is mechanically very difficult and expensive.

In the present invention, different chemical sample compounds are provided at spaced intervals along a strip or filament constructed of a non-reactive substrate to produce a linear array. A library comprising a plurality of strips having various chemical sample compound arrays is then provided in a kit along with a support frame. A user can then arrange a subset of strips chosen from the library in the frame. By selecting among the strips, a user can construct a semi-customized array of chemical sample compounds in the frame. The present invention, therefore, provides a cost effective way of manufacturing custom arrays.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Are claims 41, 43, 45 - 46, and 48 unpatentable under 35 U.S.C. Section 103(a) over Gross, U.S. Patent 4,867,946 in view of Zuk, U.S. Patent 4,281,061? Is claim 44 unpatentable over Gross in view of Zuk and further in view of Adams, U.S. Patent 6,156,494? Are claims 49 - 52 unpatentable over Gross in view of Zuk and further in view of Bentsen, U.S. Patent 6,372,895?

VII. ARGUMENT

Background. Claim 41 recites a chemical screening kit. The chemical screening kit includes a library of strips of a non-reactive substrate. Each strip supports different linear arrays of chemically reactive substances spaced along a longitudinal axis. A support frame is provided to receive and hold different combinations of a subset of the library of strips to provide a semi-custom array of reactive substances, which can then be mutually exposed to a material to be screened.

Claim 41 has been rejected as unpatentable under 35 U.S.C. Section 103(a) over Gross, U.S. Patent 4,867,946 in view of Zuk, U.S. Patent 4,281,061. The Examiner asserts that Gross teaches all of the elements of the claim with the exception of a kit. Zuk is cited for disclosing a kit of reagents, for teaching that it is convenient to provide reagents in a kit, and

for motivating one to provide the reagents in a kit in pre-measured amounts to eliminate the variability that can occur when performing an assay.

The Gross Reference. Gross discloses an analysis device that evaluates test strips that have been exposed to urine. Referring to the Figures, the device includes a holder 13 for receiving test strips and a sensing head 14 including light sources for photometrically analyzing the test strips 9. When a green light is illuminated, a test strip 9 is moistened with urine and deposited on the holder 13, and the test strips provided on the holder 13 are then photometrically analyzed. The test strips 9 each have identical linear arrays of chemically reactive substances (bilirubin, urobilinogen, etc.), and are analyzed with a maximum of two wavelengths of light. After the test is performed, the holder and work platform 15 can be cleaned and reused.

The Zuk Reference. Zuk describes a kit for performing immunoassays. The kit includes predetermined amounts of dry reagents provided in a predetermined ratio selected to optimize the sensitivity of an assay in a range of interest. The reagents in the kit are reconstituted in an aqueous medium for testing. In essence, therefore, Zuk discloses a kit for performing an immunoassay in which the end user is required to do nothing but add water.

The Combination of Gross and Zuk Does Not Teach All of the Elements of the Rejected Claims.

As noted above, the Examiner asserts that Gross teaches all of the elements of the claim with the exception of a kit. Gross, however, provides a method for urine analysis in which a series of identical test strips are analyzed using photometric analysis. Gross neither teaches nor suggests the concept of providing a library of test strips having different linear arrays of chemical compounds which can be combined together to provide a semi-custom planar array. On the contrary, as all of the test strips disclosed by Gross are identical, the

array provided on the holder of the device for analysis will always be the same, and cannot be customized in any way.

Gross, furthermore, teaches a method in which the test strips are positioned on the frame after they are exposed to the material to be screened, here specifically urine. Gross does not teach or suggest providing the strips on a frame, and then exposing all of the strips simultaneously. Rather, as these individual test strips are clearly intended to provide the same test on different samples of urine, the different strips cannot be exposed simultaneously. Gross therefore not only does not suggest exposing the test strips provided on the holder to a material to be screened, Gross teaches away from such a concept.

Contrary to the assertion of the Examiner, therefore, Gross teaches neither a library of test strips having different arrays of chemical compounds, a frame for holding subsets of the library of strips for mutual exposure to a material to be screened, or any method for providing a semi-customized array of reactive substances. Zuk, which fails to disclose any type of test strip or frame, also does not disclose these elements. Therefore, the combination of Gross and Zuk does not provide all of the elements of claim 41, and the Applicant respectfully requests that the rejection of claim 41 and associated dependent claims 43 - 52 be overturned.

One of Ordinary Skill Would Not Be Motivated to Combine Gross and Zuk.

The Examiner further asserts that it would have been obvious to one of ordinary skill in the art to take the reagents and other materials as taught by Gross and format them into a kit because Zuk teaches "that it is convenient to do so and one can enhance the sensitivity of a method by providing reagents as a kit along with other materials. One in the art would be motivated to because the reagents in a kit are available in pre-measured amounts which eliminates the variability that can occur when performing an assay."

Providing the test strips disclosed by Gross in a kit, however would neither "enhance the sensitivity of a method" nor "eliminate variability". The test strips disclosed by Gross

already include pre-measured amounts of reagents, and therefore there is no need to eliminate variability. Providing a number of strips in a kit, moreover, would not increase the sensitivity of any test performed with a strip. The sensitivity of each individual strip would clearly remain the same.

More importantly, the purpose of the present invention is not to eliminate variability. The purpose of the present invention is to enable variability by allow an end user to vary the elements in a planar array to customize a test array. Zuk therefore not only does not suggest a kit as recited in the claims, Zuk teaches away from such a kit. Therefore, the Examiner has provided no reasonable motivation to combine the cited references to provide a kit as recited in claim 41, and the Applicant respectfully requests that the rejection of claims 41 and 43 - 52 be overturned for this reason as well.

VIII. CONCLUSION

The cited combination of Gross and Zuk, therefore, does not teach all of the elements of claims 41 and 43 - 52. Moreover, there is no reasonable motivation to combine these references. Therefore, the Applicants respectfully request that the rejection of claims 41 and 43 - 52 be overturned.

Respectfully submitted,

David C. Schwartz

Dated: March 6, 2006

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APPENDIX A

Listing of Claims

Claim 1. (canceled)

Claim 2. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the strips have a length taken along the longitudinal axis of at least ten times the maximum cross-sectional dimension of the strips taken across the longitudinal axis.

Claims 3 - 4. (canceled)

Claim 5. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the non-reactive strips are glass fibers.

Claim 6. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the support frame holds the strips transversely spaced in parallel relationship.

Claim 7. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the support frame holds the strips transversely spaced along two perpendicular axes.

Claim 8. (canceled)

Claim 9. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the strips include recessed portions receiving the chemically reactive substances.

Claim 10. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the strips include a marker allowing the strips to be distinguished.

Claim 11. (previously presented): The semi-custom array for chemical screening of claim 10 wherein the marker is selected from the group of printing and fluorescent material.

Claim 12. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the strips include a marker allowing a given end of the strip to be identified.

Claim 13. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the marker is selected from the group of printing and fluorescent material.

Claim 14. (withdrawn): A chemical screening apparatus comprising a strip of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, oligonucleotides exposed on a surface of the strip.

Claim 15. (withdrawn): The chemical screening apparatus of claim 14 wherein the strip has a length taken along the longitudinal axis of at least ten times the maximum cross-sectional dimension of the strip taken across the longitudinal axis.

Claim 16. (withdrawn): The chemical screening apparatus of claim 14 wherein the non-reactive strip is a glass fiber.

Claim 17. (withdrawn): The chemical screening apparatus of claim 14 wherein the strips include isolating bands of a chemically repellant coating between the chemically reactive substances.

Claim 18. (withdrawn): The chemical screening apparatus of claim 14 wherein the strips include recessed portions receiving the chemically reactive substances.

Claim 19. (withdrawn): The chemical screening apparatus of claim 14 wherein the strips include a marker allowing the strips to be distinguished.

Claim 20. (withdrawn): The chemical screening apparatus of claim 14 wherein the marker is selected from the group of printing and fluorescent material.

Claim 21. (withdrawn): The chemical screening apparatus of claim 14 wherein the strips include a marker allowing a given end of the strip to be identified.

Claim 22. (withdrawn): The chemical screening apparatus of claim 1 wherein the marker is selected from the group of printing and fluorescent material.

Claim 23. (withdrawn): A method of manufacture of strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip comprising the steps of;

(a) affixing the strips in a frame to be transversely spaced in parallel relationship in a plane to expose at a plane, surface locations for the chemically reactive substances;

(b) immersing the frame in a sequence of component solutions;

(c) light activating the bonding of a substance of the component solution with the strips at a subset of the locations for each component solution; and

(d) releasing the strips from the frame.

Claim 24. (withdrawn): A method of manufacture of strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip comprising the steps of;

(a) positioning the strip to have different longitudinal portions positioned in adjacent volumes holding different component solutions;

(b) light activating the bonding of a substance of at least one of the component solutions with the strip at a location for at least one of the chemically reactive substances;

(c) repositioning the strip within the volumes of different component solutions; and

(d) repeating steps (b) and (c) to create chemically reactive substances at the locations.

Claim 25. (withdrawn): The method of claim 24 wherein multiple strips are simultaneously positioned within the adjacent volumes to have light activated bonding of the component solution.

Claim 26. (withdrawn): The method of claim 24 wherein the volumes are separated by a multiple of the separation of the locations of the chemically reactive substances.

Claim 27. (withdrawn): The method of claim 26 wherein the strip is formed in a continuous loop to circulate through the volumes.

Claim 28. (withdrawn): A method of manufacture of strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip comprising the steps of;

(a) positioning a plurality of strips to pass through a volume bracketing a segment of the strips;

(b) fill the volume with component solution bonding onto the segments a portion of the chemically reactive substances;

(c) flush the volume of component solution;

(d) repositioning at least some of the strip within the volumes so that different segments are subtended; and

(e) repeating steps (b) and (c) with different chemical solutions to create the chemically reactive substances at the locations.

Claim 29. (withdrawn): The method of claim 28 wherein the strips are independently repositioned so that each strip may have different chemically reactive substances with respect to the others.

Claim 30. (withdrawn): A method of manufacture of strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip comprising the steps of;

(a) affixing the strips in a frame to be transversely spaced in parallel relationship in a plane to expose at a plane, surface locations for the chemically reactive substances;

(b) placing a mask material over the plane exposing a selected subset of locations;

(c) immersing the frame in a sequence of component solutions;

(d) repeating steps (b) and (c) for a plurality of masks and component solutions to create the different chemically reactive substances; and

(e) releasing the strips from the frame.

Claim 31. (withdrawn): A method of manufacture of beads of a non-reactive substrate supporting different, chemically reactive substances exposed on a surface of the strip comprising the steps of:

(a) preparing strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced at locations along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip by repeated exposure of the locations to different chemical materials in a predefined sequence; and

(b) cutting the strip between the locations to produce the beads.

Claim 32. (withdrawn): A method of screening chemical materials comprising the steps of:

(a) preparing at least two different strips of a non-reactive energy conductive substrates extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip;

(b) arranging the strips to cross at a read-out site;

(c) applying energy to at least one of the strips to promote an energetic interaction with a chemically reactive substance at the read-out site; and

(d) detecting energy at least one of the strip to detect the energetic interaction at the read out site.

Claim 33. (withdrawn): A method of promoting localized chemical reactions comprising the steps of:

(a) preparing least two different strips of a non-reactive energy conductive substrates extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip;

(b) arranging the strips to cross at a promotion site;

(c) applying energy to at least one of the strips to promote an energetic interaction with a chemically reactive substance at the promotion site causing the localized chemical reaction.

Claim 34. (canceled)

Claim 35. (previously presented): A semi-custom array for chemical screening comprising:

(a) at least two different strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip; and

(b) a support frame for receiving and holding the strips for mutual exposure to a material to be screened wherein the strips include isolating bands of a chemically repellant coating between the chemically reactive substances.

Claims 36 - 40. (canceled)

Claim 41. (previously presented): A chemical screening kit comprising:

(a) a library of strips of a non-reactive substrate extending along a longitudinal axis, each strip supporting, spaced along that longitudinal axis, different linear arrays of chemically reactive substances exposed on a surface of the strip; and

(b) a support frame for receiving and holding different combinations of a subset of the library of strips for mutual exposure to a material to be screened;

whereby a semi-custom array of reactive substances may be created.

Claim 42. (canceled)

Claim 43. (previously presented): The chemical screening kit of claim 41 wherein the strips have a length taken along the longitudinal axis of at least ten times the maximum cross-sectional dimension of the strip taken across the longitudinal axis.

Claim 44. (previously presented): The chemical screening kit of claim 41 wherein the non-reactive strips are glass fibers.

Claim 45. (previously presented): The chemical screening kit of claim 41 wherein the support frame holds the strips transversely spaced in parallel relationship.

Claim 46. (previously presented): The chemical screening kit of claim 41 wherein the support frame holds the strips transversely spaced along two perpendicular axes.

Claim 47. (previously presented): The chemical screening kit of claim 41 wherein the strips include isolating bands of a chemically repellant coating between the chemically reactive substances.

Claim 48. (previously presented): The chemical screening kit of claim 41 wherein the strips include recessed portions receiving the chemically reactive substances.

Claim 49. (previously presented): The chemical screening kit of claim 41 wherein the strips include a marker allowing the strips to be distinguished.

Claim 50. (previously presented): The chemical screening kit of claim 41 wherein the marker is selected from the group of printing and fluorescent material.

Claim 51. (previously presented): The chemical screening kit of claim 41 wherein the strips include a marker allowing a given end of the strip to be identified.

Claim 52. (previously presented): The chemical screening kit of claim 41 wherein the marker is selected from the group of printing and fluorescent material.

EVIDENCE APPENDIX

No additional evidence is provided.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

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FEE TRANSMITTAL
For FY 2006

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 500.00

Complete if Known	
Application Number	09/638,102
Filing Date	August 11, 2000
First Named Inventor	David c. Schwartz
Examiner Name	Davis, Deborah A.
Art Unit	1641
Attorney Docket No.	960296.97133

METHOD OF PAYMENT (check all that apply)

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FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	**Fee ($)**	**Fee ($)**	**Fee ($)**	**Fee ($)**	**Fee ($)**	**Fee ($)**	**Fees Paid ($)**
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	**Fee ($)**	**Small Entity Fee ($)**
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		**Extra Claims**	**Fee ($)**		**Fee Paid ($)**
_____	- 20 or HP =	_____	x _____	=	_____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		**Extra Claims**	**Fee ($)**		**Fee Paid ($)**
_____	- 3 or HP =	_____	x _____	=	_____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims

Fee ($)	**Fee Paid ($)**
_____	_____

3. APPLICATION SIZE FEE

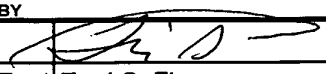
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		**Extra Sheets**		**Number of each additional 50 or fraction thereof**	**Fee ($)**		**Fee Paid ($)**
_____	- 100 =	_____	/ 50 =	_____ (round up to a whole number)	x _____	=	_____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Appeal Brief	$500.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 41,756	Telephone 414-277-5229
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This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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